



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,847	03/17/2004	Thomas Hermann	250350US	3961

22850 7590 08/09/2006

C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

KIM, ALEXANDER D

ART UNIT PAPER NUMBER

1656

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,847

Applicant(s)

HERMANN ET AL.

Examiner

Alexander D. Kim

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 48-53 and 60-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 48-53 and 60-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/058,945.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office actions, a non-Final rejection (mailed on 02/23/2006), Applicants filed a response and amendment received on 06/07/2006. Said amendment cancelled Claims 47 and 54-59, amended Claims 46, 49-53 and 60-64. Thus, Claims 46, 48-53 and 60-65 are pending in the instant Office action.

Priority

2. As previously noted, the application claim for benefit of a prior-filed application 10/058945 filed 30 January 2002, under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c), noted in the transmittal and the amended first page of the specification is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/058,945 filed on 30 January 2002. This foreign priority is in German, without English translation.

English translations of Germany patent applications 101 32 946.6 and 101 10 760.9 have been filed on 06/07/2006.

Withdrawn-Objections to the Specification

2. Previous objection of the title is withdrawn by virtue of Applicant's amendment.

Maintained-Objections to the Specification

3. Previous objection of the Abstract is maintained because it continues to not disclose the source species (*Corynebacterium glutamicum*). The amendment of Abstract discloses a broad term of "coryneform bacterium" instead. Moreover, the amendment to the Abstract is improper without appropriate markings to changes. Correction is required.

Withdrawn-Claim Objections

4. Previous objection of a Claim 61 because of the term "acteoglutamicum" is withdrawn by the virtue of Applicant's amendment.
5. Previous objection of a Claim 62 because the "and" is missing at the end of a list is withdrawn by the virtue of Applicant's amendment.
6. Previous objection of Claims 62 and 64 because of a missing period at the end of claim is withdrawn by the virtue of Applicant's amendment.

Withdrawn-Claim Rejections - 35 USC § 112

7. Previous rejection of Claim 62 under of 35 U.S.C. 112, second paragraph, as being indefinite for the limitation of lysE "code for lysine export" at the end of claim is withdrawn by virtue of Applicants' amendment to "codes for a lysine export protein".
8. Previous rejection of Claims 55-56 under 35 U.S.C. 112, first paragraph, new matter, is withdrawn by virtue of Applicants' amendment canceling Claims 54-59.
9. Previously rejected Claims 46 and 54-65 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by the virtue of Applicants' amendment. The instant Reply to Office Action contains typographical error in the argument regarding to the instant rejection. The examiner notes the "Claims 47" on page 7 bottom should be --- Claim 46---. It has been treated as Claim 46 according to the correct citation in the following page 8.
10. Previous rejection of Claim 46 and 54-65 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' amendment.
11. Previous rejection of Claims 62 is withdrawn by the virtue of Applicant's amendment.

Maintained-Claim Rejections - 35 USC § 112

12. Previous rejection of Claim 64 under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Claim 64 recites the limitation “the Zwa2 protein” and as noted in the previous Office action, there is insufficient antecedent basis for this limitation in the claim. Appropriate clarification of Claim 64 is required.

13. Previous rejection of Claims 49-50 under 35 U.S.C. 112, first paragraph, new matter, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the specification at page 12, lines 11-16 clearly supports these claims citing “the expression of the otsA gene product is reduced at least 5%” in Claim 49 and “10%” in Claim 50. However, the Applicants argument by directing to the specification page 12, lines 11-16, which cites activity or concentration is “**reduced to**” (emphasis added): “0 to 10% or 0 to 5%” (having 10% and 5% activity at most), is clearly different from the scope of Claims 49 and 50 having as about 95% (reduced by 5%) and about 90% (reduced by 10%) activity or concentration. For the reasons above, the instant rejection is maintained.

14. Previous rejection of Claims 62 and 63 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. As previously noted, to fully describe a genus of feedback resistant lysC, applicants must (1) fully describe at least

Art Unit: 1656

one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. In the absence of structural/functional correlations, one of skill in the art would be unable to predict the structure of the members of the genus from the instant disclosure.

Applicants note two US patent number 5,688,671 and 6,893,848 and the specification on page 25-27. Applicants note that these US patents describe the structure of a feedback resistant aspartate kinase encoded by the *lysC*. However, these patents describe only one species from a *Corynebacterium glutamicum*, which cannot sufficiently represent the genus of *lysC* for **all** feedback resistant aspartate kinase. The art teaches how to overexpress the *lysC* from a *Corynebacterium glutamicum*, which happened to be a feedback resistant aspartate kinase. However, the genus *lysC* also encode a non-feedback resistant aspartate kinase. The disclosure of one species in the instant specification and said US patent documents do not sufficiently describe the structure for a genus of **any** feedback resistant aspartate kinase including a feedback resistant aspartate kinase derived from a non-feedback resistant aspartate kinase by recombinant technology, for example, thus one skilled in the relevant art would not possess the claimed genus invention. For the reasons above, the instant rejection is maintained.

15. Previously rejected Claims 62-64 under 35 U.S.C. § 112, first paragraph, written description, which are drawn to method involved in an increased amount of “the Zwa1 protein” and/or a lysE; the instant claim 64 is drawn to method involved in a decreased amount of “the Zwa2 protein” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that each of the “lysE, zwa1 and zwa2 genes are known in the art and by citing “as described in the specification on page 25-27”. However, the instant specification discloses the one specific gene(s), which does not represent a genus of **any** Zwa1, lysE and a Zwa as described in previous Office action. For the reasons above, the instant rejection is maintained.

16. Previously rejection of Claims 46, 48-53 and 60-65 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that a modified bacteria with “a deletion in the otsA gene was cultured” for “the increased level of the amino acid lysine” in the Example. A partial or full deletion of otsA gene for modification is enabled by the specification and the prior art. However, mutations of “repressor genes, activator genes, operators” or “attenuators” (see p. 20, lines 5-10) as a part of genetic modification that is not enabled because the instant specification did not disclose a single example and the prior art do not teach such mutations in the coryneform bacterium. Thus it is unpredictable and requires undue

Art Unit: 1656

experimentations to practice a full scope of claims. For the reasons above, the instant rejection is maintained.

17. Previously rejected Claims 62 and 63 under 35 U.S.C. 112, first paragraph, scope of enablement, for methods using an increased amount of any aspartate kinase is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that "the specification on page 25-27" disclose a "genes and their correspond proteins/enzymatic products are known in the art" in the Applicants' Argument. Applicants are enabled for a method of using the specific lysC gene disclosed in the specification page 25-27. However, the disclosed lysC gene does not allow anyone to predict the claimed genus to increase the amount of **any** aspartate kinase genes, and also satisfy the limitation of being feed back resistant by the instant disclosure. Thus, the lysC gene disclosed in the specification does not satisfy factors that are considered in the previous office action, to practice a full scope of claimed genus in Claim 62 and 62. For the reasons above, the instant rejection is maintained.

18. Previously rejected Claims 62 and 63 under 35 U.S.C. 112, first paragraph, scope of enablement, while being enabling for method using an increased amount of *Corynebacterium glutamicum* lysE and zwa1, does not reasonably provide enablement for method using an increased amount of gene products for any lysE and zwa1, is maintained. Applicants' arguments have been fully considered but are not deemed

Art Unit: 1656

persuasive for the following reasons. Applicants argue that “the specification on page 25-27” disclose a “genes and their correspond proteins/enzymatic products are known in the art” in the Applicants’ Argument. Applicants are enabled for a method of using the one gene disclosed in the specification page 25-27. However, the lysE and the zwa 1 gene disclosed in the specification do not allow anyone to predict and practice claimed genus that is increase the amount of **any** lysE and **any** zwa 1 genes. Thus, the *Corynebacterium glutamicum* lysC and zwa1 gene in the specification does not satisfy factors that are considered in previous office action to practice full scope of claimed genus in Claims 62 and 62. For the reasons above, the instant rejection is maintained.

Withdrawn-Claim Rejections - 35 USC § 102

19. Previous rejection of Claims 46, 48, 60-62 and 65 under 35 U.S.C. 102(e) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS) is withdrawn by virtue of Applicants providing a certified English translation of foreign priority documents (filed on 1/30/2001 and 3/7/2001) which disclose supports for Claims 46, 48, 60-62 and 65.

Maintained-Claim Rejections - 35 USC § 102

20. Previous rejection of Claims 49 and 50 under 35 U.S.C. 102(b) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS) is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive for the reason of the priority date for claims 49 and 50 remains the instant

Art Unit: 1656

application's filing date, March 17, 2004 (see new matter rejection maintained). For the reasons described above, the instant rejection is maintained.

21. Previous rejection of Claims 51-53 under 35 U.S.C. 102(e) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS) is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants provided two certified English translation of foreign priority documents (filed on 1/30/2001 and 3/7/2001). However, these foreign document does not support limitations of the otsA gene product is reduced at least 25%, 50% and 75% in Claims 51, 52 and 53, respectively. For the reasons above, the instant rejection is maintained.

22. Previous rejection of Claims 49 and 50 rejected under 35 U.S.C. 102(a) as being anticipated by Tzvetkov et al. (Microbiology (July 2003), 149, pp 1659-1673) is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the reason described above. Thus, the priority date for claims 49 and 50 remains the instant application's filing date, March 17, 2004. For the reasons above, the instant rejection is maintained.

Summary of Pending Issues

23. The following is a summary of the issues pending in the instant application:
- a. The Abstract stands objected to for not completely describing the disclosed subject matter.

- b. Claim 64 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite, for lacking antecedent basis for "the Zwa 2 protein".
- c. Claims 49-50 stand rejected under 35 U.S.C. 112, first paragraph, for the new matter(s).
- d. Claims 62 and 63 stand rejected under 35 U.S.C. § 112, first paragraph, written description, which are drawn to methods using a lysC, which codes for a feed-back resistant aspartate kinase.
- e. Claims 62-64 stand rejected under 35 U.S.C. § 112, first paragraph, written description, which are drawn to method involved in an increased amount of "the Zwa1 protein" and/or a lysE; or involved in a decreased amount of "the Zwa2 protein".
- f. Claims 46-53 and 60-65 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for a reduction of Coryneform bacterium otsA gene expression by modification of "repressor genes, activator genes, operators" or "attenuators" (see p. 20, lines 5-10).
- g. Claims 62 and 63 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for methods using an increased amount of any feedback resistant aspartate kinase.
- h. Claims 62 and 63 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement, while being enabling for method using an increased amount of *Corynebacterium glutamicum* lysE and zwa1, does not reasonably provide enablement for method using an increased amount of gene products for any lysE and zwa1.
- i. Claims 49 and 50 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS).
- j. Claims 51-53 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ohtaki et al. (USPAP 2002/0137150 filed on 2 Jul. 2001 as cited in IDS).
- k. Claims 49 and 50 stand rejected under 35 U.S.C. 102(a) as being anticipated by Tzvetkov et al. (Microbiology (July 2003), 149, pp 1659-1673).

Conclusion

24. Claims 46, 48-53 and 60-65 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
July 28, 2006


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER